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PATENT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Ronald A. Coffee	: Paper No:	
Serial No.	09/758,716	: Group Art Unit:	3761
Filed:	January 11, 2001	: Examiner:	Kim M. Lewis
For:	DISPENSING DEVICE AND METHOD FOR FORMING MATERIAL		

RESPONSE TO RESTRICTION REQUIREMENT AND AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action, dated April 19, 2004, setting forth a restriction requirement in the above patent application, please consider the following remarks.

In the Office Action, the Examiner has requested that the Applicant make an election between the following twelve groups of claims, which the Examiner contends represent twelve independent or distinct inventions. The Examiner has grouped the claims as follows:

I. Claim 42, drawn to a method of forming an ingestible product containing an active ingredient, classified in class 128, subclass 200.11;

II. Claim 43, drawn to a method of forming at least partially solid material, classified in class 239, subclass 690;

III. Claim 44, drawn to a hand-holdable woundcare device, classified in class 239, subclass 3;

IV. Claims 45 and 46, drawn to a device to produce fiber particles, classified in class 427, subclass 30;

V. Claims 47-49, 59, 61, and 65-67, drawn to a method of providing a wound dressing, a method of forming a dressing for a wound, a method of providing a dressing on a surface, a method of providing a dressing on a wound, a method of forming a dressing or covering on a surface, and a method of providing a dressing or covering on a surface, classified in class 602, subclass 41;

VI. Claims 50-54 and 56, drawn to a method of promoting or controlling tissue repair in a wound, a method of providing a tissue repair-promoting dressing for a wound, a method of controlling or promoting tissue repair, classified in class 424, subclass 93.7;

VII. Claim 55, drawn to a hand-holdable device for enabling promotion of tissue repair, classified in class 239, subclass 691;

VIII. Claims 57 and 60, drawn to a method of providing a fiber covering on a surface, and a method of providing a fibrous layer covering on a surface, classified in class 2, subclass 243.1;

IX. Claim 58, drawn to a method of supplying an active ingredient to an area of skin or soft tissue, classified in class 604, subclass 290;

X. Claim 62, drawn to a method of depositing material into a cavity or on to a concave surface, classified in class 604, subclass 11;

XI. Claim 63, drawn to a method of producing material for supply to the respiratory system of a mammal, classified in class 128, subclass 200.24; and

XII. Claim 64, drawn to a method of forming a cavity wound dressing, classified in class 604, subclass 19.

The Applicant respectfully traverses the restriction requirement for the following reasons. The Examiner contends that the twelve groups of claims represent twelve distinct inventions. In reviewing this restriction requirement, it is noted that these inventions have been divided only into seven different classes, not twelve:

1) class 2 – apparel, (claims 57 & 60);
2) class 128 – surgery, (claims 42 and 63);
3) class 239 fluid spraying, sprinkling and diffusing, (claims 43, 44 and 55);
4) class 424 – drug, bio-affecting and body treating compositions, (claims 50-54 and 56);
5) class 427 – coating processes, (claims 45 and 46);
6) class 602 – surgery: splint, brace or bandage, (claims 47-49, 59, 61 and 65-67); and
7) class 604- surgery, (claims 58, 62 and 64).

Since several claims share common classes as well as overlapping subject matter, the Examiner would not be placed under an undue burden by combining these claims because they share common classes and would necessarily be searched by the Examiner at the same time. Thus, at the very least and based on these classifications, some claims should be combined to provide only seven different groups.

Arguably, the claims of groups V, VIII, X and XII could also be combined since all of these groups of claims deal with a method of forming a wound or surface dressing which is comprised of fibers or fibrils (albeit different classifications). This combination includes claims 47-49, 57, 59-62, and 64-67. Therefore, if a complete search is performed for group V, which is drawn to a method of providing and/or forming a wound dressing, groups VIII, X and XII will also be searched, since all of these claims also relate to a method of forming a fibrous wound covering and/or dressing.

MPEP §803 indicates that even if a patent application contains independent and distinct inventions, those inventions should be considered together by the Examiner if s/he can do so without any undue burden. Therefore, even assuming arguendo that the claims of groups V and VII, X and XII do define four separate inventions, the Examiner can consider all of them without placing herself under an undue burden since they all relate to methods of forming a wound or surface dressing which is comprised of fibers or fibrils. Therefore, the claims of groups V, VIII, X and XII of the present application should be considered together.

Since several groups of claims can be considered together without placing any undue burden on the Examiner, the restriction requirement given by the Examiner, which attempts to define twelve separate inventions, is not appropriate in the present case. Accordingly, withdrawal of this restriction requirement is requested and

issuance of an office action covering claims 47-49, 57, 59-62, and 64-67 (groups V, VIII, X and XII) of the present application is earnestly requested.

In the event that the Examiner does not withdraw the restriction requirement and prosecute claims 47-49, 57, 59-62, and 64-67 together, then the Applicant provisionally elects the claims of Group V, claims 47-49, 59, 61, and 65-67, for prosecution on the merits in the present application.

In addition to electing the claims of group V, the Applicant also wishes to submit the following NEW claims for consideration. As in the group V claims, these new claims are also directed to "a method of providing a wound dressing, a method of forming a dressing for a wound, a method of providing a dressing on a surface, a method of providing a dressing on a wound, a method of forming a dressing or covering on a surface, and a method of providing a dressing or covering on a surface," and may be classified in class 602. They, therefore, should be considered along with the other claims the Examiner has placed in group V.

Please add in the following NEW claims:

68) (NEW) A method of providing a wound dressing, the method comprising:

a) supplying liquid to at least one outlet;

b) subjecting liquid at an outlet to an electric field thereby causing the liquid to form at least one jet of electrically charged liquid, the liquid being such that after formation the at least one jet forms charged fibers which are attracted to and deposit onto a surface to form a mat.

69) (NEW) The method of claim 68 wherein the fibers comprise a bioresorbable inert polymer.

70) (NEW) The method of claim 69 wherein the polymer is selected from the group consisting of polyhydroxybutyric acid, polyvinyl alcohol, polyglycolic acid, polylactic acid and mixtures thereof.

71) (NEW) The method of claim 69 or 70 wherein the fibers further comprise at least one active component.

72) (NEW) The method of claim 71 wherein the active components are selected from the group consisting of analgesics, antiseptics, antibiotics, bactericides, antifungals, antiparasitics, anti- inflammatory agents, fibrinogen, vasodilators, proteolytic enzymes, cytokines, fibroblast growth factor (FGF), epithelial growth factor (EGF) , thrombin, transforming growth factor (TGF), cells, peptides,

polypeptides, insulin, immune suppressants, stimulants, vaccines, and mixtures thereof.

73) (NEW) The method of claim 72 wherein the active component is selected from thrombin, fibrinogen and mixtures thereof.

74) (NEW) The method of claim 68 wherein at least a portion of the fibers include collagen, and at least a portion of the fibers include at least one active component selected from thrombin, fibrinogen and mixtures thereof.

75) (NEW) The method of claim 73 wherein the bandage is adapted for application to a burn.

76) (NEW) The method of claim 68 wherein more than one layer of fibers is deposited to form the bandage.

77) (NEW) The method of claim 76 wherein skin cells are interspersed between fiber layers.

78) (NEW) The method of claim 71 wherein the active ingredients further comprise cytokines.

79) (NEW) The method of claim 68 wherein the fibers are coated with a surfactant.

80) (NEW) The method of claim 71 wherein different active components are provided in the different layers.

81) (NEW) A method of forming a hemostatic dressing, said method comprising electrohydrodynamically processing liquid comprising at least one active ingredient selected from fibrinogen, thrombin and mixtures thereof, to form a fibrous mat.

82) (NEW) The method of claim 81 wherein said liquid comprises at least one additional active ingredient selected from the group consisting of analgesics, antiseptics, antibiotics, bactericides, antifungals, antiparasitics, anti- inflammatory agents, vasodilators, proteolytic enzymes, cytokines, fibroblast growth factor (FGF), epithelial growth factor (EGF), transforming growth factor (TGF), cells, peptides, polypeptides, insulin, immune suppressants, stimulants, vaccines, and mixtures thereof.

83) (NEW) The method of claim 81 wherein the method further comprises electrohydrodynamically processing thrombin at one polarity so as to rapidly coalesce with droplets of opposite polarity comprising fibrinogen to form a fibrin mat.

84) (NEW) The method of claim 81 wherein at least a portion of the fibers include collagen, and at least a portion of the fibers include at least one active component selected from thrombin, fibrinogen and mixtures thereof.

85) (NEW) The method of claim 81 wherein the step of electrohydrodynamically processing comprises processing matter comprising thrombin at one polarity so as to rapidly coalesce with matter of opposite polarity comprising fibrinogen to form a fast-reacting fibrin mat.

86) (NEW) A wound dressing formed by supplying liquid to at least one outlet; subjecting liquid at an outlet to an electric field thereby causing the liquid to form at least one jet of electrically charged liquid, the liquid being such that after formation the at least one jet forms charged fibers which deposit onto a surface to form a mat; and the fibers comprise a bioresorbable inert polymer.

87) (NEW)The wound dressing of claim 86 wherein the fibers further comprise one or more active components.

88) (NEW) The wound dressing of claim 87 wherein the active components are selected from the group consisting of analgesics, antiseptics, antibiotics, bactericides, antifungals, antiparasitics, anti- inflammatory agents, fibrinogen, vasodilators, proteolytic enzymes, cytokines, fibroblast growth factor (FGF), epithelial growth factor (EGF), thrombin, transforming growth factor (TGF), cells, peptides, polypeptides, insulin, immune suppressants, stimulants, vaccines, and mixtures thereof.

89) (NEW)The wound dressing of claim 88 wherein the active components are selected from fibrinogen, thrombin, and mixtures thereof.

90) (NEW)The wound dressing of claim 86 wherein at least a portion of the fibers include collagen, and at least a portion of the fibers include at least one active component selected from thrombin, fibrinogen and mixtures thereof.

91) (NEW) The wound dressing of claim 86 wherein the polymer is selected from the group consisting of polyhydroxybutyric acid, polyvinyl alcohol, polyglycolic acid, polylactic acid, and mixtures thereof.

92) (NEW) The wound dressing of claim 86 wherein the dressing comprises more than one layer of fibers.

93) (NEW) The wound dressing of claim 92 wherein skin cells are interspersed between fiber layers.

94) (NEW) The wound dressing of claim 86 wherein the mat is formed by electrohydrodynamically processing thrombin at one polarity so as to rapidly coalesce with matter of opposite polarity comprising fibrinogen to form a fast-reacting fibrin mat.

95) (NEW) The wound dressing of claim 86 comprised of more than one layer.

96) (NEW) The wound dressing of claim 86 wherein cells are dispersed between the layers.

97) (NEW) A pre-formed, stable hemostatic dressing comprising fibers wherein the dressing is formed by subjecting to an electric field a liquid comprising an active ingredient selected from fibrinogen, thrombin, and mixtures thereof.

98) (NEW)The dressing of claim 97 wherein said liquid is processed by EHD processing.

99) (NEW)The dressing of claim 98 wherein the fibers comprise a bioresorabable polymer.

100) (NEW)The dressing of claim 99 wherein the polymer is selected from the group consisting of polyhydroxybutyric acid, polyvinyl alcohol, polyglycolic acid, polylactic acid, and mixtures thereof.

101) (NEW) The dressing of claim 99 wherein the fibers comprise an additional active ingredient selected from the group consisting of analgesics, antiseptics, antibiotics, bactericides, antifungals, antiparasitics, anti- inflammatory agents, vasodilators, proteolytic enzymes, cytokines, fibroblast growth f actor (FGF), epithelial growth factor (EGF), transforming growth factor (TGF), cells, peptides, polypeptides, insulin, immune suppressants, stimulants, vaccines, and mixtures thereof.

102) (NEW)The dressing of claim 99 wherein said dressing is adapted for application to an external surface.

103) (NEW)The dressing of claim 99 wherein said dressing is adapted for application to an internal surface.

No new matter is introduced as a result of these new claims. Antecedent basis for these new claims is set forth in the following chart: (column and line numbers refer to US Patent 6,252,129, which is the parent of this pending application).

Claim Number	Antecedent Basis
68	abstract, col. 1, line 67; col. 2, line 3
69	col. 2, lines 53-54
70	col. 2, lines 53-57
71	abstract; col. 2, line 65; col. 3, lines 23-40
72	col. 11, lines 40-59
73	col. 13, line 66; col. 14, lines 9 and 11
74	col. 3, line 42; col. 13, line 66; col. 14, lines 9 and 11
75	Fig. 4 text; col. 9, lines 1-3
76	col. 11, line 30
77	col. 11, line 66
78	col. 11, line 48
79	col. 3, line 37
80	col. 11, lines 60-67
81	col. 14, lines 11-12; col. 13, line 66; col. 14, line 9 and 11
82	col. 11, lines 40-59
83	col. 14, lines 9-12
84	col. 3, line 42; col. 13, line 66; col. 14, lines 9 and 11
85	col. 3, line 42; col. 13, line 66; col. 14, lines 9-12
86	abstract, col. 1, line 67;

	col. 2, line 3; col. 2, lines 53-54
87	col. 3, lines 9-11
88	col. 11, lines 40-59
89	col. 13, line 66; col. 14, lines 9 and 11
90	col. 3, line 42; col. 13, line 66; col. 14, lines 9 and 11
91	col. 2, lines 53-57
92	col. 9, line 35; col. 2, lines 59-61; Fig. 10; col. 4, lines 36-37
93	col. 11, line 66
94	col. 14, lines 9-12
95	col. 9, lines 1-8; col. 11, lines 60-63; col. 13, lines 17-19
96	col. 11, line 66
97	col. 2, lines 39-42; col. 14, lines 11-12; col. 13, line 66; col. 14, lines 9 and 11; col. 9, lines 39-42
98	col. 3, lines 46-49
99	col. 2, lines 53-54
100	col. 2, lines 53-57
101	col. 11, lines 40-59
102	col. 1, line 10
103	col. 1, line 10

Respectfully submitted,

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